

Powering Your mHealth-enabled Trials with Medidata Patient Cloud

Now more than ever, the life science industry is moving towards a more patient-centered approach to healthcare. This is a great opportunity to engage patients and create better partnerships with them. The clinical trial space is an excellent channel to leverage mobile health (mHealth) technologies. mHealth provides data that is real-time, continuous and objective; and it also provides data that was previously inaccessible, so we can understand if the patient is indeed getting better from their treatment.

Patient Cloud is the mHealth solution that captures data from apps and wearable sensors to accelerate patient-centric clinical research. Using Patient Cloud, studies can capture a richer, more complete dataset, improve the patient experience and run more efficient trials. By “instrumenting” patients with sensors, wearables and apps, researchers gain a better understanding of patient outcomes, from response to therapy to the potential for digital biomarkers. As part of the Medidata Clinical Cloud®, Patient Cloud offers unprecedented visibility into the patient experience, providing researchers with nuanced insight into patients’ progress and the safety and efficacy of therapies.



Comprehensive ecosystem of apps and sensors

Quick and easy access to technology is an important consideration for every mHealth-enabled trial. Medidata Patient Cloud’s comprehensive ecosystem of apps and sensors is designed to meet these needs. Patient Cloud enables patient data collection through an electronic patient-reported outcomes (ePRO) app for Android and iOS devices and a software development kit (SDK) to support additional mobile apps. Setting up an mHealth-enabled trial, capturing and accessing data are further simplified by Patient Cloud’s pre-integrated access to over 200 sensors.

Clinically relevant, reliable mHealth data

Medidata understands the importance of moving your trials safely and efficiently through regulatory pathways to market. For this reason, we’ve ensured that the data aggregators have secure authentication; that data ingestion and cloud storage is scalable and flexible for your trial’s needs; and that there is a complete, unified audit trail that meets regulatory standards. So even though you will receive rapid delivery of your clinical mHealth data, the way you receive it will always be safe and compliant with regulations. This means that you can focus on how well the patients are doing under treatment.

The Value of mHealth

- **Better data.** mHealth provides better data, which promotes better science. mHealth technology harnesses more objective, continuous and nuanced data. It also captures previously inaccessible data, providing you with a fuller picture of the patient and of the safety and efficacy of treatments.
- **Improved patient experience.** Mobile technologies allow patients to go about their day with less intrusion from the studies they participate in, which means better patient compliance and the opportunity to reduce site visits. mHealth also has the potential to readily update patients on study information and keep them engaged in the trial, allowing them to comply to protocol more easily.
- **Greater trial efficiency.** Since mHealth data arrives directly from the source, data collection requires no transcription and therefore moves at a faster pace. Data is cleaner and no manual data entry is needed, which means less burden on the sites.

Unified data and deep operational insights

We enable seamless integration with clinical data in the Medidata Clinical Cloud, expertise in implementation of apps and sensors as well as visualization dashboards and analytics to provide key clinical trial insights.

Medidata Patient Cloud: The Solution to Your mHealth-enabled Trials

Patient Cloud is Medidata's mobile health solution for collecting patient-centric data in a regulatory compliant manner for clinical research. It consists of three ways to collect and integrate data into the Medidata Clinical Cloud:

ePRO is a mobile app that collects responses to questionnaires and diaries.

- Text- and scale-based questionnaires configured easily within Medidata Rave® EDC with no custom development
- Flexible implementation model delivered as full-service or fully enabled
- Available on iOS and Android

AppConnect is an SDK to integrate existing or custom apps with the Medidata Clinical Cloud.

- Ability for developer to build mobile app front-end while Medidata manages back-end data flow
- Flexibility to gather and process data from nearly any type of app
- Compatible with Apple ResearchKit

SensorLink is a data ingestion platform that collects data from biosensors and wearables.

- Access to over 200 consumer and medical grade sensors
- Summary views of data in Rave, and full raw data streams for detailed analysis and dashboards
- Visualization and analytics dashboard, our charter innovation program to view patient compliance and data quality

About Medidata

Medidata Solutions is the leading global provider of cloud-based solutions for clinical research in life sciences, transforming clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud® brings new levels of productivity and quality to the clinical testing of promising medical treatments, from study design and planning through execution, management and reporting. We are committed to advancing the competitive and scientific goals of global customers, which include over 90% of the top 25 global pharmaceutical companies; innovative biotech, diagnostic and device firms; leading academic medical centers; and contract research organizations.

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Medidata Clinical Cloud®

Cloud-based clinical research solutions | Innovative technology | Data-driven analytics
Reduced costs | Improved time to market | Faster decisions | Minimized risk